REMARKS

This paper is responsive to the Office Action mailed October 9, 2002. Presently, claims 1-21 stand rejected.

Claims 1-2, 4-5, 10-13 and 15-20 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al. (US 5,792,124) in view of Park et al. (US 6,159,187). According to the Examiner, Horrigan discloses a catheter or sheath having features in common with the claimed invention, but does not teach the use of a flat wire coil as a reinforcement means. Park was cited for its teaching of a catheter section having a "braided wire coil", as shown in Fig. 7. Applicant respectfully traverses this rejection.

The present invention is directed to an introducer sheath. Optimally, such sheaths should have a thin-walled construction and be resistant to kinking. When an introducer sheath kinks during a medical procedure the sheath becomes unusable and cannot be straightened. As a result, the sheath must be removed, thereby leaving an enlarged, bleeding opening which typically cannot be reused for percutaneous entry. Increasing the thickness of the sheath wall in an attempt to avoid kinking is undesirable because the increased wall thickness reduces the ability of the sheath to pass through narrow bodily passageways. In addition, this increased wall thickness necessitates enlargement of the entry hole, which is also undesirable.

Even though it is well known that an introducer sheath should be thin-walled, Horrigan nonetheless chose to utilize a wire braid fused to the inner catheter liner as a reinforcement means, rather than a wire coil as in the present invention. It is known in the art that the use of a wire braid reinforcement provides favorable torsional control when compared to a wire coil (torsional control being a stated objective of Horrigan). However, it is also known in the art that a wire braid enjoys little kink resistance when compared to a wire coil. In addition to the lack of kink resistance, a braided reinforcement also has an enlarged diameter when compared to a wire coil, resulting, primarily, from the crossing of the wire strands that make up the braided pattern. When a key objective of such introducer sheaths is to achieve smaller and smaller diameters, the use of a wire coil is therefore advantageous. In addition, another advantage of the use of a wire coil in an introducer sheath is the ease of manufacture of the sheath. When a braid is utilized, it is necessary to fuse or otherwise bond

(at least) the ends of the braid to the inner liner. Otherwise, the high tensile strength of the braid tends to cause the braid to spring outwardly and not wrap around the liner. In addition, the terminal ends of a braid are prone to fraying. This necessitates that the ends of the braid be well-bonded or fused to the outer wall of the inner liner to avoid such frayed ends. A wire coil, on the other hand, may simply be compression fitted around the inner liner within the outer tube. Normally, no fusing or bonding of the coil (as in Horrigan), or its ends, is required. As a result, the use of a wire coil reinforcement rather than a wire braid in an introducer sheath reduces the cost of manufacture of the sheath. Thus, an introducer sheath utilizing a wire coil enjoys numerous advantageous over a wire braid.

The Park reference teaches a catheter section that is capable of self-forming a selected shape upon application of heat and retaining that shape upon cooling. Specifically, the catheter section includes a forming member which comprises a super-elastic nickel-titanium (nitinol) alloy. The reference addresses the problem of accessing remote regions of the human anatomy. A catheter section is formed in a first shape, and is then restrained in a polymeric outer sheath in a second shape under non-equilibrium conditions. When the polymeric outer layer is heated (and thereby softened), the catheter section re-assumes the shape given to it during the heat treatment step. In the ideal case, the physician is able to use one or other of the two shapes in a particular situation. Preferably super-elastic nitinol ribbon braids are used for reinforcement, because of their ability to retain non-elastic strain and return to a prior form upon release of the polymeric restraint. Col. 7, lies 55-60. Thus, this reference deals with the problem of accessing remote anatomical areas in a completely different manner than the present invention.

As stated, the present invention utilizes a wire coil rather than a wire braid, to obtain the advantages of, among others, kink resistance, small wall diameter and low manufacturing cost. The Horrigan reference neither teaches nor suggests an optimal manner of achieving such advantages, and in fact, teaches away from such advantages. Park teaches the use of a super-elastic nickel-titanium braid member. Neither of the references appreciates the advantages provided when a coil is used, as in the present invention.

Flexibility at the distal end of the sheath is a key feature of the present invention. For the tubing to bend without kinking, the material on the outer part of the bend must stretch,

and the material on the inner part of the bend must compress. The very nature of a braid (overlapping woven fibers or filaments) is such that a braid resists expansion and compression. This resistance to expansion and compression is what gives braid reinforced tubes their kink resistance. However, the mere combination of lower durometer materials with a braid reinforcement defeats the purpose of the lower durometer materials and results in a tube that is only marginally more flexible. The use of a coil reinforcement, on the other hand, can elongate or increase the distance between the turns on the inside of the bend very easily with absolute minimum force. Combining the coil reinforcement with the lower durometer materials results in a tube structure that is much more flexible and kink resistant.

Neither Horrigan nor the other cited references recognize the importance of the coil to flexibility. In fact, the Horrigan construction results in a tip portion that is dominated by the properties of the braid. The illustrations in the present application show the coil in plan view, in a manner which makes it clear that the inner and outer layers will have the ability to stretch and compress as necessary, and allows true flexibility that is a function of the polymer layers and not the reinforcement.

The use of a reinforcement composition such as that taught in the Park reference adds complexity and manufacturing cost to a catheter. Park does not address the desire to reduce costs, as in the inventive sheath. Furthermore, although Park mentions that kink-resistance is a desirable feature of such catheters, it does not teach or suggest the straightforward manner in which such problem is addressed in the present invention. Applicant respectfully submits that absent the use of hindsight gleaned from the teachings of the present invention, one skilled in the art would not combine such disparate teachings to arrive at the claimed invention. This is particularly so in view of the preference that the references show to the use of a wire braid, rather than a coil, as in claim 1 of the present application. Therefore, for all of the foregoing reasons, Applicant respectfully submits that claim 1 is not obvious in view of the cited combination.

Claims 2, 4-5, 10-13 and 15-20 are dependent, directly or indirectly, on claim 1, and include all of its limitations. Therefore, these claims are allowable for at least the same reasons that claim 1 is allowable.

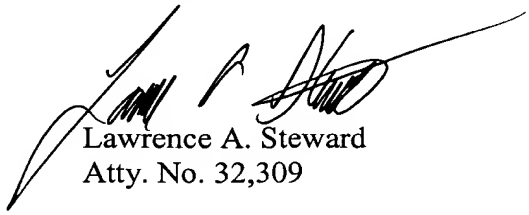
Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of Parker (US 5,380,384). Claims 6-9 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of Ju et al (US 5,599,325). Claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of MacDonald et al (US 6,210,396).

According to the Office Action, Parker was cited for its teaching of an inner tube having a roughed outer surface. Ju was cited for its teaching of an outer sheath tube made from a blend of a polymer and a radiopaque filler. MacDonald was cited for its teaching of an outer tube comprising first and second tube sections of different colors. Applicant respectfully submits that nothing in these teachings overcomes the shortcomings recited above with regard to the rejection of claim 1.

Claim 2 has been amended to establish proper antecedent basis.

Based upon the foregoing, Applicant respectfully submits that all claims 1-21 are in condition for allowance. Accordingly, Applicant respectfully requests the issuance of a Notice of Allowance. If the Examiner believes that the prosecution of this application may be expedited by a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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MARKED-UP COPY OF CLAIMS:

2. (Twice Amended) The introducer sheath according to claim 1, wherein said first and second outer tubes [and said inner tube] are bonded to each other and to said wire coil, and to said inner tube between windings of said wire coil.